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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,412	08/21/2003	David N.S Hon	29290.01	7755

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EXAMINER	
LEITH, PATRICIA A	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 06/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/645,412	HON ET AL.	
	Examiner	Art Unit	
	Patricia Leith	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 22-24 are pending in the application and were examined on their merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a previous Office Action.

Terminal Disclaimer

The terminal disclaimer filed on 1/13/05 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US 6,149,947 A has been reviewed and is accepted. The terminal disclaimer has been recorded.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 22-25 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 28 and 30-31 of copending Application No. 09/716,890. This is a provisional obviousness-type double patenting rejection. In the Instant case, Claims 28, 30 and 31 of '890 teach a method for enhancing wound healing comprising application of an active ingredient of inorganic solids comprising potassium ions, zinc ions calcium ions and rubidium ions. The claims of '890 do not specifically teach wherein the pH has a range of approximately 4-7, or wherein the pharmaceutically acceptable carrier is selected from ointments and creams for example

However, the Specification of '890 which is the parent case to this Instant application, clearly teaches that the preferred pH of the compositions are 4-7 (p.4) and that carriers such as ointments and creams were suitable for use in the composition (p. 4). Thus, the Instant claims are obviated by '890.

Claim Rejections - 35 USC § 112

Claim 24 remains rejected under 35 USC 112 first paragraph for the reasons of record.

Applicant has not provided convincing arguments in order to overcome this rejection. Applicant argues that the ailments which are currently claimed in claim 24 find support in the Instant specification. The Examiner respectfully disagrees that the Instant specification is enabling for any type of skin cancer such as K. sarcoma or melanoma for example. The Instant specification as filed does not provide any indication or data which would verifiably demonstrate that the composition of the Instant claims will work commensurate in scope with this claim. The state of the art is quite unpredictable with regard to cancer treatments as keenly pointed out in the previous Office Action.

Applicant's response essentially argues that 35 U.S.C. 112, first paragraph, permits an artisan to present claims of essentially limitless breadth so long as the specification provides one with the ability to test any particular embodiment which is

encompassed by the material limitations of a claim and thereby distinguish between those embodiments which meet the functional limitations from those embodiments which don't. This argument is not entirely without merit. However, the issue here is the breadth of the claims in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan and the guidance presented in the instant specification and the prior art of record. This make and test position is inconsistent with the decisions in *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), *Amgen v. Chugai Pharmaceuticals Co. Ltd.*, 13 USPQ2d, 1737 (1990), and *In re Wands*, 8 USPQ2d, 1400 (CAFC 1988). *In re Wands* stated that the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and, (8) the breadth of the claims.

The Examiner has keenly discussed these factors in the original Office Action. It is deemed, in light of knowledge obtained from the state of the art that successful cancer therapies are gravely unpredictable. There are *no working examples* found in the Instant specification which indicates that the composition of the Instant claims will perform beneficially on any type of cancer such as melanoma. Since there are **no** working examples, then one must consider the guidance provided by the instant specification and the prior art of record. The state of the art indicates that cancer does

not share etiologies with acne or psoriasis and that cancer is difficult to treat and has no cure. No nexus has been established in the prior art, nor in the Instant specification as filed between treatment of skin disorders such as acne and treatment of often fatal cancers such as melanoma. Therefore, the species of diseases found in the Instant claims such as melanoma for example, do not bear any reasonable correlation to skin disorders such as acne.

Thus, it is deemed that the scope of the Instant claims do not possess a reasonable amount of predictability in light of the teachings of the state of the art, the lack of representative examples in the Specification and the lack of any reasonable scientific explanation of why the composition of the Instant claims would be even *relatively* effective toward cancer. Therefore, to practice the instant invention in a manner consistent with the breadth of the claims would not require just a reasonable, routine repetition of the work that is described in the instant application but a substantial inventive contribution on the part of a practitioner which would involve expensive, time consuming trial and error protocols.

The first paragraph of 35 U.S.C. 112 requires that the breadth of claims must be based upon the predictability of the claimed subject matter and not on some standard of trial and error. To argue that one can make material embodiments of the invention and then test for those that work in the manner disclosed or that the instant claims only encompass the working embodiments is judicially unsound. Unless one has a

reasonable expectation that any one material embodiment of the claimed invention would be more likely than not to function in the manner disclosed or the instant specification provides sufficient guidance to permit one to identify those embodiments which are **more likely to work that not** without actually making and testing them then the instant application does not support the breadth of the claims.

The inadequate disclosure coupled with a lack of representative examples and the art recognized unpredictability with respect to the treatment of cancer preclude the making and use of compounds within the scope of the presently claimed invention by the skilled artisan without undue experimentation.

Applicant's arguments with regard to the rejections under 35 USC 102(b) and (e) were fully considered. Applicant's principal argument concerning the rejections under 35 USC 102(b) and (e) is that neither prior art reference taught the pH of the compositions. The Examiner concedes and hence the previous rejections are hereby removed.

Claim Rejections - 35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 22-24 are rejected under 35 U.S.C. 103(a) as obvious over Carmel, A. (8/1991) in light of Genis et al. (US 6,458,338)* in view of Berger et al. (US 5,458,881).

Additionally, Claims 22-24 are rejected under 35 U.S.C. 103(a) as obvious over Genis et al. (US 6,458,338) in view of Berger et al. (US 5,458,881).

The teachings of Carmel and Genis et al. were keenly described in the previous Office Action. Neither reference specifically taught that the pH of their compositions was at a pH range of approximately 4-7.

Berger et al. (US 5,458,881) taught that "it is often necessary to locate the pH of cosmetic compositions at approximately 5.5, namely at a pH approximately that of the skin, to decrease their aggressiveness to the skin" (Col.1, lines 47-50).

The statement regarding pH in the claims reads 'has a pH of approximately 4-7". The term 'approximately' is not defined in the Specification, and therefore the Examiner has given this term it's broadest meaning within reason. Specifically, the Examiner deems that 'approximately 4-7' means about 3.5 to about 7.5.

One of ordinary skill in the art would have been motivated to formulate either of the compositions disclosed by Carmel or Genis et al. to a pH in the range of approximately 4-7, specifically to a pH of approximately 5.5 in order to create a cosmetic which was delicate on the skin; i.e., 'pH balanced'. Therefore, it is well known in the cosmetic art that topical compositions are routinely formulated to the pH of skin. Rarely, except in the case of chemical peels, are cosmetics outside of this pH range. It is noted that neither reference stated that their cosmetic was intended for use as a chemical peel.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

*This reference is being cited merely to relay an inherent property of dead sea minerals and is not used as a basis for this particular rejection *per se*.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached from 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Leith
Primary Examiner
Art Unit 1654

6/9/05